INTRAOCULAR PROSTHESES

CROSS REFERENCE TO RELATED APPLICATIONS

This is a continuation-in-part of copending U.S. patent application Ser. No. 07/070,783, filed July 7, 1987, and hereby incorporated by reference, now U.S. Pat. No. 4,865,601.

BACKGROUND OF THE INVENTION

1. Field of Invention

This invention relates to intraocular optical lenses. More particular this invention relates to a prosthesis for replacing a part of the cornea of the eye, which has suffered for example several corneal damage, and relates to a prosthesis for replacing the posterior lens of the eye which has variable power.

2. Prior Art and General Background

There are many cases of corneal blindness, caused by severe alkali burns, immunological disorders (e.g. Stevens-Johnson syndrome) cicatrical mucous membrane pemphigiod, or severe dry eyes where regular keratoplasty is not practical or has repeatedly failed. These corneas are often grossly opague and densely vascularized with uneven thicknesses, associated with dense anterior and posterior synechiae, shallow or flat anterior chambers and cataracts or aphakia. In these situations only replacement of the cornea by a penetrating static keratoprosthesis effectively helps the patient. Current prosthetic designs require living tissue to bind to, through and around a hard ploymethylmethacrylate (PMMA) prosthesis.

Keratoconus is a progressive disease of the cornea, which often results in an outward protrusion of the central area of the cornea, causing a thinning and disfigurement of the central cornea tissue Since the cornea is basically a refracting surface for light rays received from the atmosphere, if the cornea is diseased with keratoconus, the resulting protrusion or cone distorts the normal refracting of the light rays, causing poor visual acuity and distortion. In addition, keratoconus is often very painful and irritable for the patient.

There are two known basic techniques which may be used to control or correct keratoconus. A first, more conventional technique, such as described in Siviglia, U.S. Pat. No. 4,601,556 issued on July 22, 1986, is to fit the patient with a special contact lens having a back or posterior surface, which is specifically designed to permit the diseased portion of the cornea to conform itself to the lens surface, resulting in both control of the keratoconus disease and improved visual acuity. Obviously, if the disease can be successfully controlled or corrected using such a special contact lens, a surgical corneal transplant can be avoided. However, for those cases in which the disease cannot be successfully controlled or corrected using a special contact lens, a surgical corneal transplant will be necessary.

Keratoplasty or corneal transplantation is a replacement of a partial (lamellar) or full (penetrating) thickness of diseased host cornea with donor tissue. Penetrating or lamellar keratoplasty may remove either a segment of, partial keratoplasty, or the entire, total keratoplasty, cornea. Improved techniques in cornea preservation, micro surgery and postoperative management have greatly increased the prognosis for penetrating keratoplasty during the past ten years. Previously "forbidden" corneal disorders are now being grafted successfully.

Although penetrating keratoplasty is quite successful, several factors can compromise the success of any graft. These include lid abnormalities, tear dysfunction states, recurrent forms of conjunctival inflammation, trigeminal dysfunction and neurotrophic keratitis, stromal vascularization, irregularities or extreme thinning of the stroma at the proposed graft-host junction, severe structural alteration to the anterior segment, active microbial or inflammatory keratitis, uncontrolled glaucoma and infancy.

When repeated grafts have failed, it is possible in an otherwise hopeless case to restore some vision by inserting a keratoprosthesis.

Initially the keratoprothesis included a rigid, fenestrated, supporting plate with a removable threaded hard optical cylinder. The fenestrations or openings were to permit ingrowth of connective tissue and improve nutrition of the anterior corneal layers. Advances in this particular art led to a mushroom shaped transcorneal keratoprothesis, such as that described in U.S. Pat. No. 4,470,159 to Peyman issued on Sept. 11, 1984. However, posterior fibrous coverings tend to extend over the optical portion, thus clouding of vision or even blindness may result, and inadequate anterior anchoring and ingrowth persists, and, although some prosthesis have remained successfully in place for years, others have been extruded in only weeks or months.

At the present time, the most commonly used prosthesis is an implant of a hard solid cylindrical polymethylmethacrylate lens in a flanged tubular element that protrudes posteriorly deep into the anterior chamber of the eye and which has biconvex anterior and posterior surfaces, forming a lens of appropriate power. The major complication with implants of this methylmethacrylate lens or "button" variety is that a firm bond between the cornea and the implant does not develop, and thus no barrier to infection from pathogens, which seems to occur subsequent to aqueous humor leakage from the anterior chamber around the optical center, is established, leading to extrusion with resulting endophtohalmitis and blindness. Secondary glaucoma may also be severe complication with this type of prosthesis, because of the destruction of the outflow tracks. Thus the inability of corneal tissue to adequately infiltrate the edges of the implant to effect stabilization of the prosthesis and prevent aqueous humor leakage is a cause of many failures of these prostheses.

Attempts have been made to provide a keratoprosthesis having a softer, more porous substrate surrounding the periphery of the cylindrical lens in the remaining lamellar cornea tissues. For the substrate, the patient's own tooth material, osterodentoceratoprostease, was used to provide the supporting structure.

Attempts have also been made to use a dacron peripheral skirt and supportive ungainal material, which have met with some postoperative success. Attempts have also been made to use a dacron velour skirted implant, but implants of this type have generally yielded unsatisfactory results. Perforations have also been replaced with radial slits, with gave for some of these embodiments better ingrowth results. However, good long term results were only obtained when implantation was accomplished by a slow surgical procedure requiring three operations, six to eight weeks apart. Although, these offered a slightly better visual field range, the